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18 19	Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.					
20	IN THE UNITED STATES DISTRICT COURT					
21	FOR THE DISTRICT OF ARIZONA					
22	IN RE: Bard IVC Filters Products Liability Litigation,	No. 2:15-MD-02641-DGC				
23		JOINT REPORT ON DETERMINING FILTER TYPE				
24 25 26	This Document Relates to: Lisa Hyde, et al. v. C. R. Bard, Inc., et al. CV-16-00893-PHX-DGC	(Assigned to the Honorable David G. Campbell)				
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Pursuant to the Court's Order dated July 26, 2018 (Doc. 12007 at 2 n.1), the Parties submit the following joint report regarding whether there is a means for determining Plaintiff Lisa Hyde's filter type prior to trial, or whether this will be an issue for the jury. The Parties, having conferred, set forth their respective positions as follows:

### **Defendants' Position**

Defendants have reviewed the case materials and, after conferring with Plaintiffs, conclude that there is no definitive means for determining whether Ms. Hyde was implanted with a G2<sup>®</sup>X or an Eclipse<sup>®</sup> Filter. It is Bard's position that this evidence should be presented to the jury as a question of fact for the jury to resolve.

#### **Factual Background.** I.

Plaintiffs identified this case as involving a G2<sup>®</sup> Filter in their Complaint (Doc. 1, 2:16-cv-00893-DGC), Plaintiff Profile Form, and Plaintiff Fact Sheet. Defendants' Exhibit 1, Plaintiffs' Profile Form at § 3.A. ("Bard G2"); Defendants' Exhibit 2, Plaintiffs' Fact Sheet ("PFS") at § II.1 ("G2®"). At the time of the bellwether selection in April 2017, Bard identified this case as involving a G2X when Ms. Hyde was proposed as a bellwether plaintiff. See Doc. 5652 at 6 ("Ms. Hyde had a G2X implanted on 2/25/2011."). At the same time, Plaintiffs identified this case as involving a G2, not a G2X or an Eclipse. See Doc. 5706 at 17 (Sealed Lodged) ("Name: Hyde; Device: G2"; "Lisa Hyde – G2"; "She . . . had a Bard G2 filter implanted."); id. at 1 n.1 ("Lisa Hyde, case no. 16-CV-00893 (G2 filter)"); id. at 25 (same); see also Doc. 5707 at 10 (Sealed Lodged) ("Hyde – G2 fracture and migration; complex percutaneous retrieval.").

As noted in previous filings (Docs. 7359, 11921), it became apparent to counsel for Bard during discovery after the bellwether selection process that there is a question of fact whether Ms. Hyde's filter is a G2X or an Eclipse Filter. Bard provided notice of this discovery to Plaintiffs nearly a year ago in its supplemental discovery responses (Doc. 11921-1), and summary judgment briefing in August 2017 (Doc 7359 at 2 n.2). Bard has subsequently determined that billing and shipping records do not conclusively answer this question, and Ms. Hyde's filter type should be a question for the jury.

#### II. Plaintiffs' Medical Records Are Not Conclusive.

On February 25, 2011, Plaintiff Lisa Hyde was implanted with a Bard Filter through a jugular approach by Dr. David Henry at Wheaton Franciscan Healthcare – Franklin ("Wheaton"). <u>Defendants' Exhibit 3</u>, Selected Plaintiff Medical Records at HYDEL\_WFHF\_RAD00002-03. There is no product sticker and no lot number identified in the medical records to confirm the filter type. Dr. Henry's implant record identifies the filter simply as a "Bard G2 retrievable." *Id.* Other records from the date of implant refer to the filter as a "G2 jugular/subclavian IVC filter." <u>Defendants' Exhibit 3</u> at HYDEL\_WFHF\_MDR00109. Because imaging shows that the filter had a snarable tip, the filter is either a G2X or Eclipse, not a G2 which lacks a snarable tip. The Eclipse is an electropolished version of the G2X Filter.

On August 26, 2014, Dr. William Kuo retrieved Ms. Hyde's filter. Dr. Kuo refers to Ms. Hyde's filter as both a G2X and Eclipse Filter in his medical records. <u>Defendants' Exhibit 3</u> at HYDEL\_SHC\_MDR00019 ("The images show an infrarenal Bard Eclipse IVC filter"), HYDEL\_SHC\_MDR\_00039 (same); HYDEL\_SHC\_MDR\_00055-56 ("Spot radiograph of the IVC demonstrates a Bard G2X filter"; "Successful retrieval of a fractured Bard G2X IVC Filter."). Thus, Plaintiffs' medical records are inconclusive on the issue.

## III. Plaintiff's Physician Deposition Testimony Is Not Conclusive.

Dr. Henry's deposition testimony is not clear on the filter model that he implanted in Ms. Hyde. When asked whether she received "a G2X IVC filter," Dr. Henry testified "I believe it may have been, but I'm not sure." <u>Defendants' Exhibit 4</u>, April 6, 2017, Dr. Henry Dep. Tr. at 11:22-24. He had no independent recollection of the encounter, which was the only encounter Dr. Henry had with Ms. Hyde. *Id.* at 12:5-12.

Dr. Kuo's testimony is equally inconclusive. Dr. Kuo testified that it is hard to distinguish between a G2X or Eclipse from imaging because "[t]hey look the same on the x-ray." <u>Defendants' Exhibit 5</u>, March 23, 2017, Dr. Kuo Dep. Tr. at 25:23 to 26:5; 24:25 to 25:1 ("The shape of the device of an Eclipse and a G2X are identical."); 23:16-22 ("It's

the same filter. One of them is just another name for when they added an electro-polish on the device. But it's pretty much the same filter."); 67:18 to 68:5 ("without having a written record, it would be hard to see that on the x-ray.").

Even after he removed the filter and actually saw the device, Dr. Kuo was still unable to definitively distinguish whether it was a G2X or an Eclipse filter. *Id.* at 24:10-15. This is because "when we remove these devices, we can't tell because we don't have an electron microscope[] in the room [to determine] whether there's an electro-polish on it." *Id.* at 24:16-25. Ms. Hyde's filter was discarded after it was retrieved, so there is no way to confirm whether it was electropolished. Thus, Plaintiffs' physician testimony is equally inconclusive no the issue.

## IV. Bard's Sales Representative Deposition Testimony Is Not Conclusive.

On February 16, 2011, Mary Starr, the Interventional Radiology Coordinator for Wheaton, e-mailed Matt Fermanich, Bard's sales representative for Wheaton at the time: "I need to order some filters is it the Eclipes [sic] or the G2?" <u>Defendants' Exhibit 6</u>, BPVEFILTER-48-00004804-07. Later that day, Mr. Fermanich responded, "Mary you want the Eclipse," and he provided product codes. *Id.* at BPVEFILTER-48-00004804. On February 17, 2011, Ms. Starr with Wheaton replied: "Thanks Matt. We still have a G2 in stock. Are those still being used?" *Id.* It does not appear after a review of the discovery in the parties' possession that Mr. Fermanich responded to this last e-mail. But Tim Hug, Bard's regional sales manager at the time, testified based on this same e-mail that he "would assume that Matt would probably tell her that the G2 -- to go ahead and utilize the G2 and that when she does her reorders to order the Eclipse. Right? I mean, that's -- that's the direction that we have, and that's the communication that we have, and I would assume that -- that Matt could carry that out, but I can't say that with certainty obviously." <u>Defendants' Exhibit 7</u>, August 23, 2017, Tim Hug Dep. Tr. at 199:9 to 200:3.

Mr. Fermanich testified that it appeared based on this e-mail that Wheaton was still "using the G2" at the time. <u>Defendants' Exhibit 8</u>, March 27, 2017, Fermanich Dep. Tr. at 202:10-22 ("Looks like it, yes."). Referring to the same e-mail, when asked whether "at

least at this time, it's fair to say that [Wheaton] is using the G2," Mr. Hug testified that it "would be fair that it sounds like they have some in stock, yes." <u>Defendants' Exhibit 7</u> at 199:9-14. This e-mail was dated eight days before Ms. Hyde was implanted on February 25, 2011. Mr. Fermanich does not know if he ever had a discussion with Wheaton before February 17, 2011, that Bard was discontinuing the G2s and that the hospital should switch to the Eclipse. <u>Defendants' Exhibit 8</u> at 202:23 to 204:5. Thus, this e-mail and related deposition testimony is also inconclusive on the issue.

# V. Bard's Sales and Billing Records Are Circumstantial Evidence That Ms. Hyde Received an Eclipse Filter.

Bard's records of IVC filter sales to Wheaton, Ms. Hyde's implanting facility, from the pertinent time period indicate that there is circumstantial evidence the filter she received on February 25, 2011, was an Eclipse. Bard acknowledges that it appears that, as of at least February 17, 2011, Wheaton "still ha[d] a G2 filter in stock," according to Ms. Starr. <u>Defendants' Exhibit 6</u> at BPVEFILTER-48-00004804. Importantly, Ms. Starr did not say that Wheaton had multiple G2 filters in stock. Instead, she said "a" filter, implying a single filter. *Id.* This appears consistent with the sales history for this facility.

Bard sold only two G2X Filters (and no other G2 filters) to Wheaton in the two years preceding the date Ms. Hyde was implanted with her filter on February 25, 2011. Defendants' Exhibit 9, BPV-17-01-00262748 (sales records from January 2010 through February 2011); Defendants' Exhibit 10, BPV-17-01-00262749 to 756 (invoices); Defendants' Exhibit 11, BPVEFILTER-28-00402336 (sales records showing zero filter sales in 2009). Both of these G2X Filters were sold in early January 2010, more than a year before Ms. Hyde received her filter. Defendants' Exhibit 10 at BPV-17-01-00262749. Critically, only one of those G2X Filters was a Jugular/Subclavian Delivery Kit, the type of delivery approach Ms. Hyde underwent. *Id.* It is unknowable whether this single G2X Filter Jugular was available for Ms. Hyde's implant on February 25, 2011.

After January 2010, however, Bard sold eight Eclipse Filters to Wheaton. Defendants' Exhibit 9. One of those Eclipse Filters was a Jugular/Subclavian Delivery Kit. <u>Defendants' Exhibit 10</u> at BPV-17-01-00262754. This Eclipse Filter Jugular was ordered on February 22, 2011, invoiced and shipped on February 23, 2011, and delivered to Wheaton on February 25, 2011 – the day Ms. Hyde received her filter. *Id.* Wheaton ordered an additional Eclipse Filter Jugular merely four days later on March 1, 2011. Defendants' Exhibit 10 at BPV-17-01-00262756.

Although Mr. Fermanich, Bard's sales representative responsible for Wheaton at the time, testified that his contact with Ms. Starr on February 17, 2011, "may have been the first opportunity I had to get to her" concerning orders for Eclipse filters, the sales records above clearly demonstrate that Wheaton had purchased Eclipse filters as early as November 2010. Defendants' Exhibit 8 at 203:19 to 204:5. Importantly, neither Mr. Fermanich nor Mr. Hug affirmatively testified as to what filter type Ms. Hyde received. Moreover, Mr. Fermanich never testified that the hospital was using G2X filters at the time of Plaintiff's implantation procedure, as Plaintiffs contend. Instead, when asked "here now we're at February 17, 2011 ... And you have ... a relatively good customer [Wheaton] who's still using the G2," Mr. Fermanich testified: "Looks like it, yes." Id. at 202:10-22; see also Defendants' Exhibit 7 at 199:9-14 (When asked "at least at this time, it's fair to say that [Wheaton] is using the G2," based on the e-mail dated February 17, 2011, Mr. Hug testified it "would be fair that it sounds like they have some in stock, yes."). Mr. Fermanich also never testified that Wheaton had yet to switch over to the Eclipse Filter by the time of Ms. Hyde's implant, even after being specifically asked: "[s]o obviously they didn't get it switched out in time for Lisa Hyde?" Defendants' Exhibit 8 at 205:5-20. The record evidence refutes this assertion.

Bard submits that it is a question of fact whether Ms. Hyde received the Eclipse Filter Jugular delivered to Wheaton the day of her implant over the G2X Filter Jugular that Wheaton purchased more than a year before her date of implant that was potentially available as late as February 17, 2011. It is Bard's position that this evidence should be presented to the jury as a question of fact for the jury to resolve.

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# VI. Bard Should Not Be Estopped From Challenging Ms. Hyde's Filter Type.

Bard should not be estopped from having the jury resolve this admitted question of fact because Bard's representation during the bellwether selection was based on inadvertence and mistake, and none of the facts and circumstances that Plaintiffs assert warrant estoppel.

Judicial estoppel is an equitable doctrine, applied at the court's discretion, which precludes a party from gaining an advantage by asserting one position, and then subsequently seeking an advantage by taking a clearly inconsistent position. See Hamilton v. State Farm Fire & Cas. Co., 279 F.3d 778, 782 (9th Cir. 2001). The Ninth Circuit invokes judicial estoppel after analyzing four factors: (1) whether the party's later position is "clearly inconsistent" with its earlier position, (2) whether the party successfully advanced the earlier position such that judicial acceptance of an inconsistent position would create the perception that the court was misled, (3) whether the party seeking to assert the inconsistent position would derive an unfair advantage if not estopped, and (4) whether the party to be estopped acted inadvertently or with any degree of intent. See Samson v. NAMA Holdings, LLC, 637 F.3d 915, 935 (9th Cir. 2011) (citing New Hampshire v. Maine, 532 U.S. 742, 749-750 (2001), and EaglePicher Inc., v. Federal Ins. Co., CV-4-870 PHX MHM, 2007 WL 2265659, at \*3 (D. Ariz. Aug. 6, 2007)). In particular, the Ninth Circuit will only apply judicial estoppel where incompatible positions are based "on knowing misrepresentation or even fraud on the court" and not "inadvertence or mistake." *Id.* (citations omitted).

This Court has consistently applied the *New Hampshire* factors, as well as the Ninth Circuit principle that judicial estoppel is not applicable in cases of inadvertence or mistake, to find judicial estoppel unwarranted. *See, e.g., Carbajal v. Dorn*, No. CV 09-0283-PHX-DGC, 2010 WL 892201, at \*2 (D. Ariz. Mar. 9, 2010) (refusing to apply judicial estoppel because "[t]he Court cannot, as a matter of undisputed fact, conclude that any change in position on the part of [the plaintiff] was based on 'chicanery' rather than inadvertence or mistake."); *Arizona v. Tohono O'odham Nation*, 944 F. Supp. 2d 748, 757

(D. Ariz. 2013), *aff'd* 818 F.3d 549 (9th Cir. 2016) (applying *New Hampshire* factors to determine that judicial estoppel was not warranted).<sup>1</sup>

First, Bard's representation to the Court in its bellwether submission that "Ms. Hyde had a G2X implanted on 2/25/2011," (Doc. 5652 at 6), was based on "inadvertence and mistake," and was in no way a "knowing misrepresentation." Samson, 637 F.3d at 935; Carbajal, 2010 WL 892201, at \*2. At the time of the bellwether selection in April 2017, it appeared based on statements in the medical records, and from a review of the imaging, that Ms. Hyde received a G2X Filter. Bard was understandably mistaken as evidenced by the inconclusive records and testimony above. Indeed, based on the same statements in the medical records, Plaintiffs themselves represented in their pleadings and discovery that Ms. Hyde received a G2 Filter. See Compl. ¶ 10 (Doc. 1, 2:16-cv-00893-DGC); <sup>2</sup> Defendants' Exhibit 1, Plaintiffs' Profile Form at § 3.A. ("Bard G2"); Defendants' Exhibit 2, Plaintiffs' Fact Sheet ("PFS") at § II.1 ("G2®").

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supplemental Defendants' Fact Sheets or the documents produced therewith.

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<sup>&</sup>lt;sup>1</sup> See also In re Smith, 526 B.R. 343, 348 (D. Ariz. 2015) (same); Am. Realty Capital Properties Inc. v. Holland, No. CV-14-00673-PHX-DGC, 2014 WL 5023004, at \*4 (D. Ariz. Oct. 8, 2014) (same); Zrihan v. Wells Fargo Bank, N.A., No. CV-12-02073-PHX-DGC, 2014 WL 348197, at \*5 (D. Ariz. Jan. 31, 2014) (same); AdVnt Biotechnologies, LLC v. Schroeder, No. CV-06-2787-PHX-DGC, 2007 WL 1875667, at \*3 (D. Ariz. June 28, 2007) (same); Tavilla v. Cephalon, Inc., 870 F. Supp. 2d 759 (D. Ariz. 2012) (same).

<sup>&</sup>lt;sup>2</sup> Bard's original, internal complaint file produced with its Defendants' Profile Form was prepared based on the only information available to Bard at the time: Plaintiffs' civil Complaint that represented that Ms. Hyde received a G2 Filter. <u>Defendants' Exhibit 12</u>, DPS\_HydeL\_CV-16-00893\_000008-21 ("Unknown G2"). Bard re-opened the complaint file once it received medical records for review. This supplemental complaint file produced with Defendants' Fact Sheet – which Plaintiffs reference in support of estoppel - was prepared again based on the only information available to Bard at the time: Plaintiffs' Complaint and the implant records from Dr. Henry identifying the filter as a "Bard G2 retrievable." <u>Defendants' Exhibit 13</u>, DFS\_HydeL\_CV-16-00893\_000003-28. This is why the supplemental complaint file referenced the product as a G2 Filter and provided the Catalog No: RF320J. Bard later re-opened the complaint file again in May 2017, after the bellwether submission, once it received the additional medical records and imaging collected during discovery. This supplemental complaint file was based on a review of these additional records, and was produced to Plaintiffs with Bard's Supplemental Defendants' Fact Sheet in August 2017. <u>Defendants' Exhibit 14</u>, DFS\_HydeL\_CV-16-00893\_000078-113. The supplemental complaint file stated "Based" on the image it cannot be determined if the filter was a G2 Express, G2X or a Bard Eclipse Filter." Id. at DFS\_HydeL\_CV-16-00893\_000080. Bard also prepared a supplemental MedWatch Submission to FDA stating "Based on the images provided, the identity of the filter cannot be determined." *Id.* at DFS\_HydeL\_CV-16-00893\_000112. Bard did not affirmatively identify Ms. Hyde's filter anywhere else in its original or

bellwether submission, and response to Bard's submission, that Ms. Hyde "had a Bard G2 filter implanted," not a G2X or an Eclipse, based on the exact same facts and circumstances that Plaintiffs claim warrant estoppel. Doc. 5706 at 17 (Sealed Lodged) ("Name: Hyde; Device: G2"; "Lisa Hyde – G2"); *id.* at 1 n.1 ("Lisa Hyde, case no. 16-CV-00893 (G2 filter)"); *id.* at 25 (same); *see also* Doc. 5707 at 10 (Sealed Lodged) ("Hyde – G2 fracture and migration; complex percutaneous retrieval."). This is clear evidence that both parties made inadvertent mistakes in their representations to the Court concerning Ms. Hyde's filter type during bellwether selection. Neither party knowingly misrepresented her filter type to the Court. *Samson*, 637 F.3d at 935; *Carbajal*, 2010 WL 892201, at \*2. The parties were simply and understandably mistaken.

More importantly, Plaintiffs repeatedly represented to the Court in their own

When Bard subsequently discovered there was a question of fact as to whether Ms. Hyde received an Eclipse or a G2X, Bard immediately notified Plaintiffs in its supplemental discovery responses (Doc. 11921-1), and in its summary judgment briefing (Doc 7359 at 2 n.2). This occurred nearly a year ago in August 2017. Plaintiffs responded to Bard's assertions in their opposition motion. Doc. 7952 at 1 n.1. Plaintiffs do not claim that they had inadequate notice of Bard's position.

Second, Bard did not seek to mislead Plaintiffs or the Court during bellwether selection with its inadvertent and mistaken representation to gain an "unfair advantage." Samson, 637 F.3d at 935. Indeed, Bard's focus in its bellwether submission was on choosing representative cases based principally on filter complications, not filter type. Bard's representations in its submission make this clear:

Ms. Hyde had a G2X implanted on 2/25/2011. Ms. Hyde's case is representative as it involves a filter fracture (25% of the pool) and also involves multiple complications in a single case including tilt, perforation, a filter strut to the heart, and a complex filter retrieval.

Doc. 5652 at 6 (emphasis added). Bard's representations concerning the other proposed bellwethers are also illustrative. *See*, *e.g.*, *id.* at 7 ("Mr. King had a G2 placed. . . . The case is representative of cases in which the allegation is that the filter tilted, perforated,

and cannot be retrieved."); see also id. at 7-8.3

Third, Bard can see no "unfair advantage" that may be derived in this case if the jury is permitted to resolve this pure question of fact. Samson, 637 F.3d at 935; Carbajal, 2010 WL 892201, at \*2. As Bard stated in its bellwether submission, "the G2 group of filters and Eclipse filters are virtually identical in configuration, the difference being that the Eclipse was electropolished." Doc. 5652 at 5. Bard maintains that the Eclipse is an improvement upon Bard's G2-line of filters. Plaintiffs throughout this litigation have consistently asserted to the contrary that the Eclipse is no different than a G2X. See, e.g., Doc. 10707 at 2-3 ("The fundamental flaw in Bard's argument is its suggestion that the Eclipse is a different device than the G2; it is not. . . . Plaintiff's experts confirm the same thing."). Plaintiffs should not now be heard that they will be prejudiced by the presentation of evidence involving the Eclipse to the jury. This Court has already admitted evidence of the Recovery® Filter's complications, testing, and design in the Jones (Eclipse) bellwether trial, over Bard's objection. Doc. 10819. Therefore, Bard will gain no "unfair advantage" from the jury's resolution of Ms. Hyde's filter type, and Bard should not be estopped because of its inadvertent representation in its bellwether submission.

Finally, Plaintiffs' other claim that Bard should be estopped because counsel for Bard "affirmatively stated" during its questioning of Dr. Henry that "we [Defendants] can establish it was a G2X," is disingenuous and without merit. Defendants' Exhibit 4 at 92:6 to 93:7. First, an attorney's statement at deposition is not evidence. Second, counsel for Bard was not making an affirmative statement to anyone, and certainly did not make a representation to gain an advantage. Third, this line is taken out of context, as counsel for Bard was clearly indicating that there was no need to further question Dr. Henry about the filter type, see id., because he had no independent recollection of the encounter, and was otherwise "not sure" whether Ms. Hyde received a G2 or a G2X. Id. at 11:22-24; 12:5-12.

<sup>&</sup>lt;sup>3</sup> This is further evidenced by Bard's opposition to Plaintiffs' proposed selections which Bard believed to be "disproportionately weighted toward the most serious types of injuries, including open surgeries, fractures of a strut to the heart, and fractures in general." Doc. 5652 at 10; *see also id.* at 10-15.

#### VII. Conclusion.

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For these reasons, it is Bard's position that this evidence should be presented to the jury to resolve the pure question of fact concerning Ms. Hyde's filter type.

#### **Plaintiffs' Position**

This case was submitted by both parties as a G2X case for consideration in the first round of the MDL bellwether process. In fact, both Plaintiffs and Defendants agreed the Hyde case should be included in the first bellwether pool of six cases set for trial. Discovery in the Hyde case was based upon the Bard G2X Filter being the subject device. As such, Plaintiffs are prepared to try a G2X case, not an Eclipse case.

Plaintiffs would not have stipulated with Defendants to include this case in the first bellwether pool for trial had both sides not agreed at the time that it was a G2X case. Trying three Eclipse cases in the first six MDL bellwethers would be deleterious to the purpose of the bellwether process.<sup>4</sup>

It is Plaintiffs' position that Defendants should be estopped from now claiming the product in question is an Eclipse, or anything other than a G2X, considering the following facts and circumstances: 5

1. The Hyde case is a defense pick. Defendants stated the following in their bellwether submission:

> Ms. Hyde had a G2X implanted on 2/25/2011. Ms. Hyde's case is representative as it involves a filter fracture (25% of the pool) and also involves multiple complications in a single case including tilt, perforation, a filter strut to the heart, and a complex filter retrieval. Ms. Hyde claims that her filter fracture caused her to experience back and abdominal pain. As such, the case gives the parties the opportunity to test their

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<sup>&</sup>lt;sup>4</sup> Again, Plaintiffs would have objected, as the Defendants have objected to trying even

one Recovery case in the first six despite the fact that it is relevant in all subsequent cases and was on the market two times longer than the Eclipse. Moreover, the values in settlement and potential jury verdicts, the parties agree, could make up 50% or more of the global settlement number of the entire litigation.

<sup>&</sup>lt;sup>5</sup> Considering the fact that the Eclipse filter was superseded by the next generation of Bard filters, the Meridian, within approximately a year and a half of clearance of the Eclipse, Defendants can agree another product would have been more appropriate and representative of the filed cases. See Eclipse and Meridian Clearance Letters, attached as Plaintiffs' Exhibit 1.

1	arguments as to these numerous complications, including any					
2	interrelationship between the complication modes.  * * * *					
3	Bard recommends that the Hyde case be second in order for					
4	trial. That case involves a G2X with fracture, with a strut embolizing to the heart. It also involves complications of tilt,					
5	perforation, and a complex percutaneous retrieval of the filter and strut by a medical doctor at Stanford University. <sup>6</sup>					
6	2. The Defendants' Fact Sheet contains numerous references to Mrs. Hyde's filter being					
7	a G2:					
8	a. Complaint Detail Record Report: "Product Name: G2 Filter; Product Catalog No: RF320J." See DFS_HydeL_CV-16-00893-000004.					
10	b. <u>Investigation Level II</u> conducted for "(Parent) Product Catalog No.: RF320J; (Parent) <b>Product Name: G2 Filter."</b> See DFS_HydeL_CV-16-00893-000010-11.					
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12	c. Complaint Trend Analysis was conducted for " <b>Product Name: G2 Filter</b> ." See DFS_HydeL_CV-16-00893-000015-18.					
13	d. MedWatch Submission was for "1. Brand Name: <b>G2 Filter System</b> – <b>Jugular."</b> See DFS_HydeL_CV-16-00893-000023.					
14	Sugular. See Dis_Hydell_e v 10 00073 000023.					
15	3. The interventional radiologist David A. Henry, M.D. who implanted the Bard filte					
16	noted in his record:					
17	Venipuncture was performed and progressive venous dilation of the tract was performed followed by placement of a <u>Bard</u>					
18	G2 retrievable sheath device in the right iliac vein.8					
19	4. Defense counsel affirmatively stated during the deposition of David A. Henry, M.D.					
20	that she need not continue questioning Dr. Henry about the identity of the produc					
21	because "we [Defendants] can establish it was a G2X.":					
22	Q. Now, to clarify, Mrs. Hyde was implanted by you with a G2X filter; correct?					
23						
24	A. I believe so. I may not have even mentioned the brand in					
25	<sup>6</sup> See Defendants' Submission Regarding Selection of Cases for Bellwether Group dated April 24, 2017, p. 6 and p. 9 (Doc. 5652), attached as <u>Plaintiffs' Exhibit 2</u> .					
26	<sup>7</sup> See Defendants' Fact Sheet documents, attached as <u>Plaintiffs' Exhibit 3</u> .					
27	<sup>8</sup> See WFH-Franklin Interventional Radiology report, signed by Debra Wiedmeyer, M.D. on behalf of David A. Henry, M.D. dated February 23, 2011					
28	HYDE_WFHF_MDR00172-73, attached as <u>Plaintiffs' Exhibit 4</u> .					

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my report.

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MR. LEIB: I'm not going to be having him answer any questions, it's privileged. He'd be having to use his expert opinion as to whether --

MS. DALY: That's fair enough.

MR. LEIB: Yeah.

MS. DALY: That's fair enough. We can establish it was a G2X. I don't need to trouble him with that.<sup>9</sup>

- 5. Bard's sales representative, Matt Fermanich, who was designated by Defendants for a deposition in the Hyde case, testified:
  - a. The hospital was using G2X Filters at time of Plaintiff's implantation procedure. 10
  - b. He does not know if he ever had a discussion with hospital personnel before Feb. 17, 2011 that Bard planned to discontinue the G2 product line and about the hospital eventually switching to Eclipse. <sup>11</sup> His testimony was based upon an e-mail to him from Mary Christine Starr of WFHC-Franklin, dated February 17, 2011, where she advised Matt Fermanich that as of February 17, 2011 the hospital still had G2 Filters in stock.
  - c. The G2 was still being sold and distributed in the sales region as late as March 8, 2011. After both the Eclipse *and* Meridian filters had launched.<sup>12</sup>
  - d. Bard was still in the process of transitioning customers from the G2 and to Meridian as late as December 13, 2011, again implying use of the G2 filters long after both the Eclipse *and* Meridian filters had launched.<sup>13</sup>
- 6. Bard regional sales manager Tim Hug testified, based on the same e-mail mentioned above from Mary Christine Starr dated February 17, 2011, that the G2 filter was stocked and available at the hospital where Plaintiff was implanted. The hospital, per directions given by sales representatives, was told to utilize the G2 filters in stock

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<sup>&</sup>lt;sup>9</sup> See Deposition of David Henry, M.D. dated April 6, 2017 at 92:6 – 93:7, attached as <u>Plaintiffs' Exhibit 5</u>.

<sup>&</sup>lt;sup>10</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 202:17-22, attached as Plaintiffs' Exhibit 6.

<sup>&</sup>lt;sup>11</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 201:16 – 204:5, attached as Plaintiffs' Exhibit 7.

<sup>&</sup>lt;sup>12</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 215:20-218:5 and Exhibit 25 to the Deposition of Matthew P. Fermanich, attached as <u>Plaintiffs' Exhibit 8</u>.

<sup>&</sup>lt;sup>13</sup> See Deposition of Matthew P. Fermanich dated March 27, 2017 at 218:6-221:9 and Exhibit 26 to the Deposition of Matthew P. Fermanich, attached as <u>Plaintiffs' Exhibit 9</u>.

before ordering Eclipse.<sup>14</sup>

- 7. After completion of Mrs. Hyde's filter retrieval procedure on August 25, 2014 at Stanford Hospital, William T. Kuo, M.D., transcribed the following in his records as his "impressions":
  - a. "1. Successful retrieval of a fractured G2X IVC filter."
  - b. "Spot radiograph of the IVC demonstrates a Bard G2X filter."
- 8. At his deposition on March 23, 2017, William T. Kuo, M.D. testified that his experience with the device allowed him to identify it as a G2X filter. <sup>15</sup>
- 9. Mrs. Hyde testified that Dr. Kuo told her the filter was a G2/G2X before her explant surgery on August 25, 2014. <sup>16</sup>
- 10. The shipping records Defendants cite are inconclusive. The records indicate that an Eclipse Jugular was shipped via 2-day shipping on February 23, 2011. There is no reference on the record or within e-mails to indicate the reason the filter was sent. Mrs. Hyde's filter was implanted 2 days later, with the procedure starting sometime shortly after 11:00 a.m. and ending around 2:00 p.m.<sup>17</sup>

It very unlikely the Eclipse Juglar would have been delivered, checked into the hospital's inventory, routed to the correct department, delivered to the doctors, and prepared for implant in time to be placed in Mrs. Hyde. Even if the Eclipse Jugular did arrive in time, as noted above, Wheaton Hospital had been told by Bard's sales representatives to use all stock G2/G2X filters and it is known that Wheaton Hospital had G2X filters in stock on February 17, 2011. As the shipping records point out, Eclipse

<sup>23</sup> See Deposition of Tim Hug dated August 23, 2017 at 197:15 – 200:3, attached as Plaintiffs' Exhibit 10.

<sup>&</sup>lt;sup>15</sup> See Stanford Hospital records, complex IVC filter retrieval dated August 26, 2015, HYDEL\_SHC\_MDR00054-56, attached as <u>Plaintiffs' Exhibit 11</u>. Deposition of William T. Kuo, M.D. dated March 23, 2017 at 23:12 – 26:5 and 28:17 – 24, attached as <u>Plaintiffs'</u> Exhibit 12.

<sup>&</sup>lt;sup>16</sup> See Deposition of Lisa Hyde dated January 25, 2017 at 39:10-40:1, attached as Plaintiffs' Exhibit 13.

<sup>&</sup>lt;sup>17</sup> See Wheaton Franciscan Hospital Records, HYDEL\_WFHF\_MDR00137-139, attached as <u>Plaintiffs' Exhibit 14</u>.

1 Femoral filters had been ordered by the hospital as early as November 2010, 4 months before Mrs. Hyde's implant procedure. The fact that Wheaton ordered Eclipse filters on 2 3 February 22, 2011 does not infer the hospital used its entire stock of G2 filters; as noted 4 above, it is clear, Mr. Fermanich was pushing Wheaton to order Eclipse filters to 5 eventually make the switch from G2/G2X. 6 Importantly, inconclusive shipping records should not be given more weight than 7 Plaintiff's implanting physician's, Dr. Henry, own notes in official hospital records which 8 he verified at his deposition. If the filter was an Eclipse, the medical records transcribed 9 by Dr. Henry would have indicated it. Dr. Henry had the experience and knowledge to tell 10 the difference and to accurately reflect the correct device in his records. 11 Therefore, Plaintiffs request the Court estop Defendants from now claiming the 12 product in question is an Eclipse and make a determination as to the identity of the Bard 13 product implanted in Mrs. Hyde. RESPECTFULLY SUBMITTED this 10<sup>th</sup> day of August, 2018. 14 15 GALLAGHER & KENNEDY, P.A. NELSON MULLINS RILEY & SCARBOROUGH, LLP 16 By: /s/ Mark O'Connor (with permission) 17 By: /s/ Richard B. North, Jr. Mark S. O'Connor (011029) Richard B. North, Jr. (pro hac vice) Georgia Bar No. 545599 18 2575 East Camelback Road Phoenix, AZ 85016-9225 Matthew B. Lerner (pro hac vice) 19 Georgia Bar No. 446986 Ramon Rossi Lopez Atlantic Station (admitted *pro hac vice*) 201 17th Street, NW / Suite 1700 20 CA Bar No. 86361 Atlanta, GA 30363 LOPEZ MCHUGH LLP 21 PH: (404) 322-6000 Phoenix, AZ 85016-9225 FX: (404) 322-6050 100 Bayview Circle, Suite 5600 richard.north@nelsonmullins.com 22 Newport Beach, CA 92660 matthew.lerner@nelsonmullins.com 23 Co-Lead/Liaison Counsel for 24 *Plaintiffs* // 25 // 26 // 27

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**CERTIFICATE OF SERVICE** I hereby certify that on this 10<sup>th</sup> day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record. s/Richard B. North, Jr. Richard B. North, Jr.